IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
1:25-cv-00368

United Therapeutics Corporation,

Plaintiff,

v.

Liquidia Technologies, Inc.,

Defendant.

DEFENDANT LIQUIDIA TECHNOLOGIES, INC.'S OPPOSITION TO PLAINTIFF'S MOTION FOR A TEMPORARY RESTRAINING ORDER

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Abbreviation	Full Term
TRO	Temporary Restraining Order
UTC	United Therapeutics Corporation
Liquidia	Liquidia Technologies, Inc.
PH	Pulmonary Hypertension
PAH	Pulmonary Arterial Hypertension
PH-ILD	Pulmonary Hypertensions Associated with Interstitial Lung Disease
NDA	New Drug Application
FDA	Food and Drug Administration
District of Delaware	United States District Court for the District of Delaware
District of DC	United States District Court for the District of Columbia
Hatch-Waxman-I	*United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-cv-755-RGA (D. Del.)
Hatch-Waxman-II	*United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 23-cv-975-RGA (D. Del.)
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APA II	*Liquidia Techs., Inc. v. FDA*, No. 1:24-cv-02428 (D.D.C.)
'782 patent	Patent No. 11,357,782 (DE 1, Ex.1)
'793 patent	Patent No. 10, 716,793
'066 patent	Patent No. 9,593,066
'901 patent	Patent No. 9,604,901
Motion	UTC's Motion for Temporary Restraining Order and Preliminary Injunction
PTAB	United States Patent Trial and Appeal Board
PTO	United States Patent and Trademark Office
PI	Preliminary Injunction
FWD	Final Written Decision
Atkins	Atkins, P., Dry Powder Inhalers: An Overview, RESPIRATORY CARE, October 2005 Vol. 50 No. 10
Selck	Declaration of Frederic Selck, Ph.D., in Support of Plaintiff's Motion for a Temporary Restraining Order and Preliminary Injunction (DE 9)
Kidder	Declaration of Douglas Kidder dated May 17, 20025

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6	Paul J. Atkins, *Dry Powder Inhalers: An Overview*, 50 RESP CARE 1304 (2005)
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11	Answer and Cross-Claims, *Liquidia v. FDA*, No. 1:24-cv-02428-TJK (D.D.C. Sept. 16, 2024), DE 30
12	U.S. Patent No. 10,716,793 B2 (Ex. A, *UTC v. Liquidia*, No. 23-cv-975-RGA (D. Del. Nov. 30, 2023), DE 8-1)
13	Non-Final Office Action for Patent Application No. 17/486,721, dated Nov. 18, 2021
14	Amendment & Request for Reconsideration for Patent Application No. 17/486,721, dated Feb. 18, 2022
15	Notice of Allowability for Patent Application No. 17/486,721, dated Apr. 21, 2022
16	Judgment and Final Written Decision, *Liquidia v. UTC,* IPR2021-00406, Paper 78 (PTAB Jul. 19, 2022)
17	Order, *Liquidia v. UTC,* IPR2021-00406, Paper 81 (PTAB Oct. 26, 2022)
18	Decision, *Liquidia v. UTC,* IPR2021-00406, Paper 82 (PTAB Feb. 2, 2023)
19	Memorandum Order, *UTC v. Liquidia*, No. 23-cv-975-RGA (D. Del. May 31, 2024), DE 96
20	Minute Entry for Motion Hearing, *UTC v. FDA*, No. 1:24-cv-00484-JDB (D.D.C. Mar. 29, 2028)

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22	Q1 2025 UTC Earnings Call Transcript, dated Apr. 30, 2025
23	Email from J. Schneider, dated May 7, 2025
24	TD Cowen: Highlights from UTHR Management Dinner, May 7, 2025
25	Q4 2024 UTC Earnings Call Transcript, dated Feb. 26, 2025
26	Refinitiv Streetevents Edited Transcript, Q4 2022 UTC Earnings Call, dated Feb. 22, 2023
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28	Refinitiv Streetevents Edited Transcript, Q1 2023 UTC Earnings Call, dated May 3, 2023
29	Letter from Michelle Sweitzer, dated Apr. 28, 2025
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31	*How to Use a Respimat Softmist Inhaler*, American Lung Association (Sept. 2022)
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35	EXUBERA Medication Guide, Jan. 27, 2006
36	Opening Expert Report of Steven D. Nathan, M.D. Regarding Infringement of U.S. Patent No. 11,826,327, *UTC v. Liquidia*, No. 23-cv-975-RGA (D. Del. Dec. 20, 2024)
37	Tyvaso DPI, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
38	Final Office Action for US Patent Application No. 17/745,333, dated May 12, 2025
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41	Final Office Action for US Patent Application No. 17/745,333, dated Mar. 17, 2024
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I. INTRODUCTION

UTC's TRO is its fourth attempt, in its third federal court, to preliminarily enjoin Liquidia from marketing its life-saving drug, Yutrepia. Twice before the District of DC in 2024 and 2025, and once before the District of Delaware in 2024, the courts denied UTC's PI because it failed to meets its burden on likelihood of success and irreparable harm. *See* Ex.1, 71–74; *UTC v. Liquidia*, 2024 WL 2805082 (D. Del. May 31, 2024); Ex.3.[1] This Court, too, should deny UTC's Motion.

UTC's Motion presents nothing new and it is just as unlikely to succeed here because UTC will not be irreparably harmed: (1) UTC delayed in filing this PI Motion; (2) UTC forecasts continued growth even when Yutrepia launches; (3) UTC executives publicly admit that Yutrepia is ***not*** a competitive threat to UTC; and (4) Liquidia can pay any monetary damages. Finally, Yutrepia does not infringe and the '782 patent is invalid. UTC's Motion should be denied.

II. STATEMENT OF FACTS

A. The Parties

UTC and Liquidia are biotechnology companies whose research and development focus includes drugs to treat the chronic conditions of PH, PAH and PH-ILD. DE 1, ¶¶1,

[1] Given the overlap of patents and subject matter in this case compared with UTC's previous unsuccessful salvos, Liquidia has moved to dismiss based on the first-filed rule, issue preclusion, claim preclusion, and the *Kessler* doctrine. *See* DE 28, 29. The threshold issues presented there preclude UTC from obtaining the relief request in its Motion.

3, 21. Liquidia expects to receive final FDA approval for Yutrepia to treat PAH and PH-ILD on May 24, 2025. *Id*., ¶¶30-31.

B. Procedural History

This case is UTC's fourth attempt, and third patent case, to keep Yutrepia off the market. In June 2020, UTC initiated the *Hatch-Waxman-I* litigation in the District of Delaware asserting the '066, '901, and '793 patents. The '793 patent was invalidated in a parallel proceeding by the PTAB; that decision was affirmed. *See UTC v. Liquidia*, 2023 WL 8794633 (Fed. Cir. Dec. 20, 2023); DE 8, 3-4. On that basis, the Delaware court in March 2024 entered judgment of non-infringement of the '793 patent. *Hatch-Waxman-I*, Ex.4; Ex.5.

In September 2023, UTC filed *Hatch-Waxman-II*, again asserting the '793 patent. Ex.2. In November 2023, UTC obtained the '327 patent and amended *Hatch-Waxman-II* to assert it. Ex.7. After the invalidity of the '793 patent was affirmed, UTC dismissed that patent from *Hatch-Waxman-II*, leaving the '327 patent. Ex.8. In February 2024, UTC moved for a PI in *Hatch-Waxman-II*, seeking to enjoin Liquidia from launching Yutrepia based on its imminent launch.[2] *Hatch-Waxman-II*, Ex.9, 4. In May 2024, the court denied the motion, holding that (1) there is a substantial question about the '327 patent's validity,

[2] UTC asserts that at the time of its failed PI motion in *Hatch-Waxman-II*, "Yutrepia™ did not have a certain launch date." DE 8, 4 n.1. UTC, however, made the same allegations of imminent launch as it makes here, telling the court that Liquidia "intends to launch" when UTC's regulatory exclusivity expires on "March 31, 2024." *Compare* Ex.9, 1, 4 to DE 8, 5-6, 18.

(2) UTC is unlikely to suffer irreparable harm, and (3) the public interest weighs against an injunction. *See Hatch-Waxman-II*, 2024 WL 2805082.

UTC also brought APA claims against the FDA in two cases alleging the FDA improperly permitted Liquidia to amend to its NDA to add the PH-ILD indication. *See APA I* Ex. 20; *APA II* Ex.11. In both cases, the courts denied UTC's requests for a TRO and PI. Ex.20; Ex.3.

One week after the denial of UTC's *APA II* PI, UTC filed this Complaint alleging infringement of the '782 patent. Although UTC purports to base infringement on an amended version of the Yutrepia NDA and label filed with the FDA in November 2024, the alleged infringing product is no different than that in *Hatch-Waxman-I* and *Hatch-Waxman-II* actions. DE 1, ¶¶19–29; DE 29, 8-10.

C. '782 Prosecution History

The '782 patent and the invalid '793 patent are closely related–they are continuations of the same application and share identical specifications. *Compare* '782 patent (DE 1, Ex.1) *with* Ex.12 ('793 patent). The claims, too, are extremely similar. Like claim 1 of the '793 patent, claim 1 of the '782 patent is directed to a "method of treating pulmonary hypertension" through an "inhalation device" with a dose containing 15-90 micrograms of "treprostinil" delivered "in 1 to 3 breaths." '782 Patent, cl.1. And like claim 4 of the '793 patent, the delivery device in the '782 patent is a dry powder inhaler. *Id.*

During prosecution of the ’782 patent, PTO Examiner Schmitt rejected the claims as obvious over the same references the PTAB found rendered the ’793 patent claims obvious. Ex.13, 2-9. He further rejected pending claim 1 as “not patentably distinct” from claim 1 of the ’793 patent under obviousness-type double patenting. *Id.*, 10-11.

In response, UTC argued the references failed to provide a reasonable expectation of success and that the claimed invention, unexpectedly “yields a successful treatment for pulmonary hypertension” and “has been copied by others.” Ex.14, 4-8.

On April 21, 2022, three months ***before*** the PTAB issued its FWD invalidating the ’793 patent, Examiner Schmitt issued a Notice of Allowance. Ex.15, 1. He allowed the ’782 patent because the claimed method was “not obvious based on the prior art as the method is not predictable.” *Id.*, 3. He also explained “it is not simple and not predictable to take the generic discloser [sic] of the prior art and predict the dose, the number of breaths, and the timing of taking the drug.” *Id.* The ’782 patent issued on June 14, 2022.

D. Invalidation of the ’793 Patent

On July 19, 2022, a month after the ’782 patent issued, the PTAB entered a FWD finding the ’793 patent invalid as obvious. Ex 16. Contrary to the ’782 prosecution, the PTAB found that the prior art teaches with a reasonable expectation of success: (1) “A method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a formulation comprising treprostinil or a pharmaceutically acceptable salt thereof”; (2) “a therapeutically effective single event dose comprising from 15 micrograms to 90

micrograms of Treprostinil"; (3) delivery of inhaled treprostinil "in 1 to 3 breaths"; and (4) "treprostinil 'is inhaled in powder form.'" *Id*., 12-18, 21, 31-35.

The PTAB also rejected UTC's argument that secondary indicia of non-obviousness (*i.e.*, unexpected results, copying and satisfaction of a long-felt need) demonstrated nonobviousness. *See id*., 22-30.

UTC appealed the decision to the Federal Circuit and Supreme Court, again with no success. *See UTC v. Liquidia*, 2023 WL 8794633, at *3 (Fed. Cir. Dec. 20, 2023), *cert. denied*, 145 S. Ct. 352 (2024). Ex.17; Ex.18

III. ARGUMENT

"[A] preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted." *Intel v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993). The "standard for granting either a temporary restraining order or a preliminary injunction is the same." *McNeill v. Bond*, 2022 WL 17526565, at *2 (M.D.N.C. Dec. 8, 2022), *R&R adopted*, 2023 WL 112542 (M.D.N.C. Jan. 5, 2023). UTC has the burden to prove: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001); *see also Feit Elec. Co. v. Cree, Inc.*, 2016 WL 1057039, at *1 (M.D.N.C. Mar. 14, 2016) ("The court must weigh the factors against each other and against the form and magnitude of requested relief."). "[A] movant cannot be granted a preliminary injunction unless it establishes both of the first two factors, *i.e.*, likelihood of

success on the merits and irreparable harm." *Amazon.com*, 239 F.3d at 1350. "While granting a preliminary injunction requires analysis of all four factors, a trial court may … deny a motion based on a patentee's failure to show any one of the four factors—especially either of the first two—without analyzing the others." *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1356 (Fed. Cir. 2002).

A. UTC Will Not Be Irreparably Injured

1. UTC's years-long delay in filing its Motion shows the lack of irreparable harm

The '782 patent issued in June 2022, but UTC waited until now to assert this patent and enjoin Liquidia's launch of Yutrepia.[3] UTC's serial PI motions prove that it believed at least by February 2024 that approval and launch of Yutrepia for PAH and PH-ILD was "imminent," yet UTC sat on its hands with the '782 patent. *See* DE 29. Accordingly, UTC's 35-month delay in asserting the '782 patent warrants denial of UTC's Motion. *See Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) ("[E]vidence that a patent owner unduly delays in bringing suit against an alleged infringer negates the idea of irreparability."); *Quince Orchard Valley Citizens Ass'n, Inc. v. Hodel*, 872 F.2d 75, 80 (4th Cir. 1989) ("Since an application for preliminary injunction is based upon an urgent need for the protection of [a] Plaintiff's rights, a long delay in seeking relief indicates that speedy action is not required.") (citation omitted); *High Tech Med. Instrumentation, Inc.*

[3] UTC's infringement allegations are based on a November 2024 Yutrepia label. DE 1, ¶¶19–29. UTC has not explained why it waited another six months to assert the '782 patent.

v. New Image Indus., Inc., 49 F.3d 1551, 1554, 1557 (Fed. Cir. 1995) (reversing grant of preliminary injunction because the patent holder's 17-month delay demonstrated "no apparent urgency to the request for injunctive relief"); *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012)(same).

2. UTC is precluded from relitigating irreparable harm

In *Hatch-Waxman-II*, UTC alleged the same economic losses and relied on basically the same expert declaration it relies on here. *See UTC*, 2024 WL 2805082; *see also* Kidder, ¶¶ 8, 13, 43. Judge Andrews rejected UTC's assertions. *See UTC*, 2024 WL 2805082, at *8–13. This Court should deem his decision preclusive. *See Astrazeneca AB v. Dr. Reddy's Lab'ys, Inc.*, 209 F. Supp. 3d 744, 753 (D. Del. 2016) ("Findings made in granting or denying preliminary injunctions can have preclusive effect if the circumstances make it likely that the findings are 'sufficiently firm' to persuade the court that there is no compelling reason for permitting them to be litigated again.")(citation omitted).

The facts here support preclusion. UTC already had the opportunity to litigate irreparable harm. Judge Andrews' decision is "sufficiently firm" because it was issued when the launch of Yutrepia for both PAH and PH-ILD was believed to be imminent; it was neither tentative nor time-limited; and he did not suggest that UTC might be able to prove irreparable injuries in the future. Ex.19. Thus, UTC should be precluded from re-litigating irreparable harm, balance of hardships and public interest before this Court. Judge Andrews' decision is, at least, *persuasive*.

3. UTC's alleged injuries are purely economic and have not been identified with specificity

"[I]t is axiomatic that purely economic injury, such as that resulting from lost sales, profits or market share, does not constitute irreparable harm sufficient to warrant injunctive relief." *Olympus Managed Health Care, Inc. v. Am. Housecall Physicians, Inc.*, 2009 WL 275779, at *2 (W.D.N.C. Feb. 3, 2009). They must be unrecoverable, great, certain, and imminent. *See Hughes Network Sys., Inc. v. InterDigital Commc'ns Corp.*, 17 F.3d 691, 694 (4th Cir. 1994). The economic injuries UTC claims fall far short of that standard.

UTC's motion consists of nothing more than already rejected general allegations of economic harm, including price erosion, lost market share, loss of goodwill, and potentially unrecoverable monetary damages. DE 8, 17-22; *UTC*, 2024 WL 2805082. Those ordinary consequences of competition are far from the "extraordinary circumstances" that "*may* give rise to the irreparable harm required for a preliminary injunction." *Hughes*, 17 F.3d at 694 (emphasis added). Here, "restraint is not justified if the only harm suffered is increased competition." *MedServ Int'l, Inc. v. Rooney*, 2006 WL 8457083, at *6 (D. Md. Mar. 21, 2006) (citation omitted).

Further, UTC and Dr. Selck do not substantiate the alleged harm, its impact, nor attempt to quantify how much UTC's prices will change or how much market share will be lost because of Yutrepia.[4] *See generally* DE 8, 17-22; Selck ¶¶68, 107, 118; Kidder

[4] Dr. Selck did previously quantify the economic harm, but chose to eliminate that quantification in his current declaration, apparently so he could provide the contradictory opinion here that the economic damage is not quantifiable. Kidder ¶67.

¶67. Quantification is critical to determine whether economic harms will be severe. *Pentair Water Pool & Spa, Inc. v. Hayward Indus., Inc.*, 2012 WL 194403, at *10 (E.D.N.C. Jan. 23, 2012) (finding no irreparable harm where plaintiff premised its PI on "conclusory" and "speculative" allegations of economic injury). At best, UTC's allegations are purely economic losses, which generally do not warrant the extraordinary relief of a preliminary injunction. *See e.g. Olympus*, 2009 WL 275779, at *2, *BellSouth Telecomm., Inc. v. MCIMetro Access Transmission Servs.*, LLC, 425 F.3d 964, 970 (11th Cir. 2005); *Heideman v. South Salt Lake City*, 348 F.3d 1182, 1189 (10th Cir. 2003) ("It is also well settled that simple economic loss usually does not, in and of itself, constitute irreparable harm"); *Hughes*, 17 F.3d at 694.

More damaging are continuous and recent statements from UTC executives that UTC will meet its growth targets—even if Liquidia launches Yutrepia—because Tyvaso is a "strongly differentiated drug device product[.]" Ex.28, 3; *see* Ex.21, 3; *see* Kidder ¶88. On ***April 30, 2025***, UTC's CEO, Dr. Rothblatt, announced that "[o]ur solid foundation built by Tyvaso, Orenitram, Remodulin and Unituxin continues to grow revenue by double digits now for 11 quarters in a row, we expect this momentum to continue, led by Tyvaso and Tyvaso DPI … ." Ex.22, 3; *see* Kidder ¶93. Speaking specifically to "potential growth trajectory" in PAH and PH-ILD given the "emerging competitor dynamic" from Liquidia, UTC's President and COO, Michael Benkowitz, stated in ***April 2025*** that "we expect to continue to grow revenues at double-digit growth with our existing portfolio heading into this year and next year." Ex.22, 8. In ***May 2025***, at an investor dinner attended by Dr.

Rothblatt and Investor Relations Manager Harry Silvers, UTC disclosed Liquidia "***is not a commercial threat*** due to undifferentiation across the board and [UTC] believes [Liquidia] will only take 5% share." *See* Ex. 23, 1 (emphasis added); Ex.24, 1-2 . This underscores how little impact UTC believes Yutrepia will have on its growth, market share, pricing and sales, despite UTC's contrary claims in its Motion.

4. UTC's fails to articulate the required nexus

To grant equitable relief, there must be a "sufficiently strong causal nexus" between the alleged harm and the allegedly infringing acts. *See Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012). The patentee must "present[] evidence that directly ties" the alleged irreparable harm to the "infringing feature" of the competing product and those features must be different from features in related patents. *Id.* at 1375; *Heart Imaging Techs., LLC v. Merge Healthcare Inc.*, 2013 WL 4432125, at *20 (M.D.N.C. Aug. 14, 2013). UTC makes no attempt to establish this nexus and instead vaguely references "some connection" between the '782 patent and Liquidia's launch of Yutrepia. *See* DE 8, 22. In fact, Dr. Selck completely ignores the nexus requirement. *See* Kidder ¶10.

This year, despite knowing that launch of Yutrepia was imminent, UTC ***increased prices*** for both Tyvaso and Tyvaso DPI "in line with what [it] typically [has] done[.]" Ex.22, 6. To support its price erosion claims, UTC relies on the November 2024 testimony of its Associate Vice President of Market Access, [redacted] DE 8, 18-19. But UTC's more recent public statements show that it began discounting Tyvaso in 2024 before Yutrepia was even

approved, let alone launched. *See* Ex.25, 4–5 (discussing rebates offered by UTC in "recent contracting efforts . . . to help position nebulized Tyvaso and Tyvaso DPI and at ***parity with current*** and potential future ***competitor products***" and confirming that "[a]t this point, we believe these additional investments and rebates have largely been pulled through, creating a new base from which Tyvaso can continue to grow.") (emphasis added). Even in the face of such discounting and the imminent launch of Yutrepia, UTC proclaimed that it has "done an amazing job in increasing [its] prescriber base as well as the depth of ILD physicians prescribing Tyvaso for [pulmonary] hypertension associated with ILD" and that it is "very confident that [its] going to meet these expectations of continuing to grow revenues at a double-digit clip with [its] existing portfolio." Ex.22, 9.

Judge Andrews also rejected UTC's allegations of lost sales and market share because the evidence shows that the market can sustain multiple, alternative treatments. *See UTC*, 2024 WL 2805082 at *11, 14-15. According to UTC's CEO, "the experience has been that when new agents have been introduced into the market, it has grown the market for all of the existing patients." Ex.26, 9-10; Kidder ¶87. CEO Rothblatt also noted, "there is so much robust room for growth and improvement in pulmonary hypertension[,]" and UTC "welcome[s] any new agent that can help the health of the pulmonary hypertension patient population." Ex.26, 9-10; Kidder ¶87.

UTC also forecasts growth in the number of patients it treats, net pricing, and net revenue, *notwithstanding Yutrepia's availability*, because Tyvaso does not, and will not, reach even half of the relevant patient population. *See* Ex.27; *see also* Kidder ¶70; *UTC*,

2024 WL 2805082, at *11. UTC's President stated that, notwithstanding Liquidia's competition, UTC was "feeling increasingly confident that there's not going to be a preference" for Yutrepia. Ex.21, 6. The doom-and-gloom predictions in UTC's Motion contradict with UTC's public statements.

That Yutrepia is not a generic version of Tyvaso also undermines UTC's claims of economic loss. Yutrepia is an innovative alternative treatment for PAH and PH-ILD, with, as UTC admits, meaningfully different characteristics that cannot be automatically substituted for any UTC product. Kidder ¶64, 87. UTC's CEO publicly admitted that Yutrepia "does not challenge our projected double-digit growth. It's because it's not a generic product, but is instead a strongly differentiated drug device product[.]" Ex.28, 3; *see also* Kidder ¶88. And just weeks ago, on April 30, Dr. Rothblatt completely undercut UTC's allegations of harm stating that new entrants, like Yutrepia, don't "steal the market" from UTC, because of the slow and cautious nature of switching treatments for life-threatening conditions, allowing UTC to be "so confident" of continued growth for "years to come." Ex.22, 10; Kidder ¶98. Dr. Rothblatt's 2025 statements to UTC investors destroys the credibility of UTC's assertions of economic harm.

5. UTC's claims of reputational harm remain speculative and unsupported

UTC's reputational harm and loss of goodwill arguments fail for the same reason they failed in its prior attempt at injunctive relief–they lack evidentiary support. DE 8, 21; *UTC*, 2024 WL 2805082, at *12; *Compare* Ex.9, 18 to DE 8, 21. That remains true today as UTC did nothing to address Judge Andrews' criticisms. UTC still relies on generalized

assertions and Dr. Selck's declaration to suggest that its reputation may suffer if Yutrepia launches and is subsequently removed from the market, but such speculative concerns are insufficient. *See* DE 8, 21; Selck ¶¶114-116; Kidder ¶¶11, 44. Courts require evidence that reputational harm is likely and irreparable, not speculative or hypothetical. *Well Cell Glob. LLC v. Calvit*, 2023 WL 6156082, at *3 (Fed. Cir. Sept. 21, 2023) (reversing preliminary injunction where plaintiff failed to establish irreparable harm, relying only on speculative assertions of potential reputational risk). UTC and Dr. Selck go so far as to argue "payors and physicians are likely to view [Tyvaso and Yutrepia] as highly similar clinical alternatives[.]" DE 8, 20; Selck ¶¶110-113. But CEO Rothblatt has publicly stated the ***exact opposite***. Ex.28, 3 (Tyvaso is a "strongly differentiated drug device product[.]"). Finally, Judge Andrews noted, but UTC ignores, that "an injunction could also injure [UTC]'s reputation if doctors and/or patients believed that [UTC] tried to keep a beneficial therapy from them." *See UTC*, 2024 WL 2805082, at *12.

6. Liquidia can compensate UTC for any monetary losses

UTC asserts that Liquidia will be unable to compensate UTC for any monetary loss because Liquidia operates at a net loss and will allegedly sell Yutrepia at "eroded prices."[5] DE 8, 21-22. UTC ignores that Liquidia has not yet launched Yutrepia, which will allow Liquidia to compensate UTC. Kidder ¶¶116-119.

[5] UTC and Dr. Selck do cite any evidence that Liquidia will sell Yutrepia at an eroded price. DE 8, 22; Selck ¶15; Kidder ¶¶53-60.

7. The Balance of Hardships Does Not Tip in UTC's Favor

Liquidia is a new market entrant, and Yutrepia will be Liquidia's primary revenue source, while UTC, a well-capitalized company, has enjoyed twenty years of market dominance and $2.33 billion in yearly revenue. Kidder ¶¶23, 114, 119-126. Given UTC's large presence, the balance of hardships tips in Liquidia's favor.[6] Further, Judge Andrews opined that the balance of harms "does not favor either party," and this Court can find the same. *UTC*, 2024 WL 2805082, at *13.

8. The Public Interest Weighs Against UTC

UTC's public interest argument boils down to keeping off the market an allegedly "lower-cost" "cheaper alternative" to Tyvaso and Tyvaso DPI. DE 8, 24. But, as Dr. Rothblatt agreed, Yutrepia is not a generic version of Tyvaso. Ex.28, 3; *see* Kidder ¶¶99. Moreover, Judge Andrews rejected UTC's "property rights" argument, instead focusing as this Court should, on the tens of thousands of patients suffering from PAH and PH-ILD. *See* DE 8, 24; *UTC*, 2024 WL 2805082, at *14-15; *Weinberger v. Romero–Barcelo*, 456 U.S. 305, 312 (1982) ("[C]ourts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction."). Absolutely nothing has changed.

As Dr. Selck notes, approximately 45,000 Americans suffer from PAH, and 30,000 to 60,000 suffer from PH-ILD. *See* Selck ¶¶35, 40. UTC "likely does not meet the current

[6] In *Hybritech Inc. v. Abbott Lab'ys.*, 849 F.2d 1446, 1456 (Fed. Cir. 1998), Abbott's (the alleged infringer) "very large presence" in its field supported an injunction. The opposite is true here.

market need." *See UTC*, 2024 WL 2805082, at *14. By its own estimates, UTC treats [redacted] of the PAH patients, less than 25% of PH-ILD patients and will not treat 50% until early next decade. *See id.* at *11; Kidder ¶69. Judge Andrews was "convinced that at least some patients would likely suffer negative consequences if [Liquidia] were enjoined from launching Yutrepia . . . ." Ex. 19. These negative consequences would multiply if Yutrepia were blocked for all indications. And for PH patients, having treatment options is critical, as different therapies work better for different patients. *See* Ex.29.

B. UTC Has Failed to Meet its Burden on Likelihood of Success

UTC must establish it will likely succeed in proving that use of Yutrepia infringes the claims of the '782 patent and that these claims are valid. *Entegris, Inc. v. Pall Corp.*, 490 F.3d 1340, 1351 (Fed. Cir. 2007). Liquidia, need only raise a "'substantial question' concerning validity, enforceability, or infringement" to defeat the motion. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997). The "substantial question" standard is "lower than what is required to prove invalidity at trial." *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1005-06 (Fed. Cir. 2009). Liquidia has raised more than a "substantial question" as to the infringement and validity of the '782 patent, warranting denial of UTC's Motion.

1. Yutrepia Does Not Infringe

"Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device[.]" *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996). Because a physician or patient using Yutrepia does not practice every limitation

of the sole independent claim of the '782 patent it likewise does not infringe any of the dependent claims. *See Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 798 (Fed. Cir. 1990). Further, because the '782 patent claims a method of treating pulmonary hypertension, UTC has the burden of establishing Liquidia has the specific intent to induce the direct infringement under 35 U.S.C. § 271(b). *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1374 (Fed. Cir. 2003). UTC fails to meet this burden as well.

The first step in determining infringement is analyzing the meaning of the asserted claims.[7] *See* DE 8, 9-10. While UTC construes certain terms in claim 1 of the '782 patent, it overlooks a critical requirement: that the administered treprostinil is "inhaled per breath through coordinated actuation of the dry powder inhaler with each breath[.]" '782 Patent, cl.1.[8] By its plain terms, this phrase requires that two separate and distinct actions—actuation and inhalation—must be coordinated. UTC's expert, Dr. Nathan, confirmed that there is no coordination required when using the Yutrepia device. DE 6, ¶155.

Claim Construction: The starting point for claim construction is the "intrinsic evidence," which consists of the patent claims, its specification and prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-17 (Fed. Cir. 2005). This in contrast to

[7] Liquidia does not concede UTC's proposed constructions are correct nor that Yutrepia meets these limitations and reserves the right to address this later.

[8] UTC and its expert, Dr. Nathan, improperly separated "being inhaled per breath" from "through coordinated actuation of the dry powder inhaler with each breath[.]" *See* DE 8, 9-10, limitations [1-g] and [1-h].

"extrinsic evidence," which consists of "expert and inventor testimony, dictionaries, and learned treatises." *Id*., 1318.

Starting with claim language, proper construction of "being inhaled per breath through coordinated actuation of the dry powder inhaler with each breath" requires coordination of the separate actions of (a) inhalation/breath and (b) actuation of the dry powder inhaler. It is claim construction canon that different words in a patent claim are presumed to have different meanings. *Symantec Corp. v. Comput. Assoc. Int'l, Inc.,* 522 F.3d 1279, 1289 (Fed. Cir. 2008). Here, "inhaled per breath," "coordinated," and "actuation," must have different meanings and each be given weight. *See Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017) ("It is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous."). "[I]nhaled per breath," therefore cannot be "actuation" and instead these two separate actions must be "coordinated." "[C]oordinated" is understood to mean consisting of "a number of actions or processes properly combined for the production of one result." Ex.30, 897.

The examples of the '782 patent confirm that inhalation and actuation are distinct actions requiring coordination. Example 2 Study iii describes the administration of treprostinil using an Optineb® pulsed ultrasonic nebulizer. '782 Patent, 14:49-65. The Optineb® device generates aerosol pulses "in cycles consisting of 2 seconds aerosol production (pulse) and 4 seconds pause." *Id*., 14:54-57. The Optineb's "opto-acoustical trigger" provides a signal to the patient indicating the specific time when the patient should

inhale from the device so inhalation is "synchronized" with "the end of the aerosol pulse, thereby providing exact dosage." *Id*., 14:57-60. Thus, the opto-acoustical trigger coordinates inhalation per breath with the actuation of the device, exactly as recited in claim 1. This same coordination is disclosed in Example 1, where the Respimat® soft mist inhaler requires the patient to coordinate pushing a button to actuate the device, resulting in puffs of aerosolized treprostinil, while inhaling. '782 Patent, 8:54-12:2; Ex. 31.

UTC positions in other proceedings involving related patents and claim language are in agreement here. These statements are considered intrinsic evidence. *See Iridescent Networks, Inc. v. AT&T Mobility, LLC*, 933 F.3d 1345, 1350 (Fed. Cir. 2019). In the IPR of related Patent 9,358,240[9], UTC argued "there are multiple pulses and breaths taken by the patient during a single event dose, and the opto-acoustical trigger ***coordinates*** the patient's breaths to ***coincide*** with the individual pulses, thereby ensuring delivery of an exact dose." Ex.32, 42 (emphasis added).

When prosecuting Patent Application 17/745,333 ("'333 application"), which is in the same family as the '782 patent, UTC again argued that the same Optineb disclosures from the specification supported pending claims expressly reciting a dry powder inhaler. *See* Ex.33, 2-3 (pending cl.1 reciting "actuation of the inhalation device coordinated with each breath"; cl.13 reciting "[t]he product of claim 1, wherein the inhalation device is a dry powder inhaler"), 7 ("The present inventors discovered that ***coordination of actuation of***

[9] *See* '782 patent, front cover "Related U.S. Application Data."

the inhalation device with each breath … provided even longer duration of pulmonary vasodilation than reported by JESC and JAHA.") (emphasis added). In support, UTC cited a declaration by Dr. Seeger from the '793 IPR that "[b]ecause we moved to such a high concentration of treprostinil in the aerosol, ***the opto-acoustical trigger to guide the patient's breathing and synchronize it to each pulse of aerosol was especially important***." Ex.34, ¶26 (emphasis added). UTC's arguments and declaration relying on coordination of inhalation and actuation in a nebulized device confirm that two separate actions, actuation and inhalation, must be coordinated for the claimed dry powder inhaler to meet this limitation.

UTC may argue that Liquidia's interpretation would read all dry powder inhalers out of the claim, but UTC is wrong. The pre-2006 literature confirms that there are dry powder inhalers requiring the same coordination between inhalation and actuation as the devices disclosed in the examples of the '782 patent. Atkins, from October 2005, describes such a DPIs and notes that typical DPIs "***obviate coordination of actuation and inspiration***" because DPIs are essentially breath-actuated, but that "breath-actuation is also one of their disadvantages." *See* Ex.6, Table 2; 1305. Atkins disclosed a DPI device that addresses these disadvantages with other DPIs, the Nektar PDS. *Id.*, Fig. 5. The Nektar DPI inhaler falls within the scope of the '782 claims, requiring the coordinated action of device actuation with the separate action of inhalation by the patient. The Nektar PDS was used in the FDA-approved insulin product, Exubra. As explained in the Exubra label, the patient must squeeze the handle to pressurize the system, push a button to fill with a cloud

of insulin, and then "[p]romptly" inhale the insulin dose. Ex.35, 10-11. Such a device, like those disclosed in the examples of the '782 patent, is the exact type of DPI required by claim 1's limitation of "being inhaled per breath through coordinated actuation of the dry powder inhaler with each breath[.]"

Non-Infringement: Yutrepia, as admitted by Dr. Nathan, is delivered via a DPI that does not require coordination of two separate events (inhalation and actuation). Instead, "the drug is released from the provided inhaler when the patient inhales with each breath" in a single action. DE 6, ¶155. The Yutrepia DPI like other passive DPIs disclosed in Atkins "obviate[s] coordination of actuation and inspiration" and thus does not meet all the limitations of claim 1. Dr. Nathan made no attempt to demonstrate that the Yutrepia DPI requires coordination between separate actions of "inhaled per breath" and "actuation" and instead implies that inhalation ***is*** actuation, which cannot the clear limitation of claim 1. Dr. Nathan's declaration here is also consistent with his testimony in *Hatch-Waxman-II*, discussing the Yutrepia device as a breath actuated DPI. Ex.36, ¶¶130, 133. Yutrepia is not administered "through coordinated actuation of the dry powder inhaler with each breath" as required by claim 1 and all dependent claims, and thus does not infringe.

Indeed, it appears that even UTC did not think the '782 patent covered breath-actuated DPIs. UTC is well versed in the interplay between FDA regulatory requirements and patents. However, UTC failed to list the '782 patent in the FDA's Orange Book for Tyvaso DPI, UTC's own dry powder inhaled treprostinil, within the statutorily mandated 30-days from patent issuance (June 14, 2022), and instead waited to list the patent until a

few weeks ago, April 24, 2025, shortly before filing the Complaint. *See* Ex.37; 21 U.S.C. §355(c)(2); 21 C.F.R. §314.53(d)(3). This late listing is conspicuous given the speed with which UTC listed its other patents in the Orange Book for Tyvaso and Tyvaso DPI during the period since the '782 patent issued. *See* Ex.37.

Finally, induced infringement requires direct infringement, which as discussed above, is lacking. *Alloc*, 342 F.3d at 1374. Further, UTC's inducement argument is a single paragraph and UTC never demonstrates that Liquidia "instructs users" to coordinate actuation with inhalation as required by claim 1. DE 8, 16.

2. The'782 Patent is Invalid

UTC contends that because the prior art from the '793 patent IPR was considered and overcome during prosecution of the '782 patent, nothing about that prior art "disrupts" the presumption of validity of the '782 patent claims. DE 8, 17. UTC is wrong. As discussed in §II.D, while the prior art from the '793 IPR was considered during prosecution of the '782 patent, UTC's arguments to overcome this art during prosecution were rejected by the PTAB in its '793 IPR FWD. Based on the '73 FWD, UTC is now estopped from arguing that the alleged differences and unexpected results that previously lead to issuance of the '782 patent. *See Allergan, Inc. v. Apotex, Inc.*, 2015 WL 13358250, at *2 (M.D.N.C. Aug. 31, 2015), *aff'd*, 681 F. App'x 955 (Fed. Cir. 2017). Indeed, Examiner Schmitt allowed the '782 patent claims over the references cited in the '793 patent IPR on the basis of UTC's arguments that a POSA would not be able to "predict the dose, the number of breaths, and the timing of taking the drug" based on the disclosures in the prior art. Ex.15,

3. However, the FWD, which was entered one month after the '782 patent issued, explicitly found that the prior art "teaches or suggests a therapeutically effective single event dose comprising from 15 micrograms to 90 micrograms of Treprostinil[,]" and "teaches or suggests" "delive[ry] in "1 to 3 breaths." Ex.16, 17-18. The PTAB determined the prior art made the dry powder claims of the '793 patent obvious. *Id.*, 31-33. Thus, contrary to the Examiner Schmitt's Reasons for Allowance, the PTAB determined that, based on the same prior art, a POSA would be able to predict the dose and number of breaths from the prior art and the other limitations of the '782 patent claims were found to be obvious. The PTAB also rejected UTC's arguments asserting objective indicia of non-obviousness including unexpected results. *Id.*, 20-30. These arguments are now completely foreclosed from UTC here.

The effect of the PTAB's '793 FWD is further underscored by UTC's current prosecution of the related '333 application at the PTO. The '333 application claims include the same limitations recited in the '782 patent. *Compare* '782 Patent (cl.1), *with* Ex.42, 2 (cl.1). In fact, in an obviousness-type double patenting rejection, Examiner Schmitt said the '333 application claims "would be required to perform the method of the '782." Ex.38, 2, 16. Examiner Schmitt, who allowed the '782 patent, has now repeatedly relied on the PTAB's reasoning and analysis from the '793 IPR FWD to reject the pending claims of the '333 application as of ***May 12, 2025***. *See* Ex.38; Ex.39; Ex.40; Ex.41, 7. This proves that had the PTAB's '793 FWD been available to Examiner Schmitt, he would have continued

to reject the '782 patent claims, thereby disrupting the validity of the '782 patent. This raises more than a substantial question as to invalidity, warranting denial of UTC's Motion.

While the PTAB's FWD does not address the timing of additional doses of treprostinil (*i.e.*, administration of an additional single event dose in the same manner occurs at least 3 hours later in claims 1-3), this limitation does not render the claims of the '782 patent valid. Examiner Schmitt, just days ago, rejected the '333 application, asserting this limitation is obvious over same prior art relied on by the PTAB to invalidate the '793 patent. *See* Ex.38, 11-12. That reasoning applies equally '782 claims. Finally, if UTC contends that the limitation requiring "coordinated actuation of the dry powder inhaler with each breath," distinguishes the prior art, "[s]uch dry powder inhalers were well known and 'widely accepted' as of 2006." Ex.13, 8 (citing Atkins).

Given the nearly complete overlap of the '782 claims with the already-invalidated '793 patent and the rejected claims of the '333 application; the lack of any patentable differences between those claims of those patents[10]; and the fact that UTC is estopped from raising these previously rejected arguments, there is a substantial question of validity sufficient to defeat UTC's Motion.

IV. CONCLUSION

For the foregoing reasons, UTC's Motion should be denied.

[10] As confirmed by the Examiner's double-patenting rejections during prosecution of the '782 patent and '333 application. Ex.13, 10; Ex.38, 16.

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Respectfully submitted,

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CERTIFICATE OF WORD COUNT

The undersigned certifies that this brief, excluding the caption, signature lines, certificates of service, cover page, tables and indexes, contains 6,157 words, as determined using the standard word count feature of the Microsoft Word program. As such, this brief is in compliance with Rule 7.3(d)(1) of the Local Rules for the Middle District of North Carolina, in that it contains less than 6,250 words.

Dated: May 19, 2025

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CERTIFICATE OF SERVICE

I hereby certify that on May 19, 2025, I electronically filed the foregoing with the United States District Court for the Middle District of North Carolina using the Court's CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the CM/ECF system.

Dated: May 19, 2025

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